

REMARKS

Claims 105, 107, 110 and 117-119 are pending. Claims 105, 110 and 118 are amended for to correct minor grammatical errors. The Amendment to the claims does not add any new subject matter.

In the Office Action, claims 105, 107, and 118-119 were rejected under 35 U.S.C. § 102(b) as being anticipated by an article described in Genomics, 1998, vol. 52, p. 192-200, Patel et al. (Patel). In the Office Action, claims 105, 107, and 117-119 were rejected under 35 U.S.C. § 102(a) as being anticipated by an article described in Journal of Human Genetics, 2002, vol. 47, p. 684-687, Nagarkatti et al. (Nagarkatti). It is respectfully submitted that all of the claims 105, 107, 110 and 117-119 are patentable over Patel and Nagarkatti for at least the following reasons.

The Patel article describes localization of the human Stat6 gene to chromosome 12q13.3-q14.1, a breakpoint region implicated in a wide variety of tumors (Abstract). However, Patel does not describe the Stat6 gene sequence being used to predict susceptibility of a human subject to atopic asthma.

It is noted that that there is a unnumbered NCBI HSSTATSIX1 gene printed-out section of a nucleotide series which has a short caption above it which mentions asthma following the Patel article, however, there is no indication of how that section is related to the Patel article. If the printed-out NCBI section was numbered, this would be page 11 with "SEQ ID NO. 1" handwritten on the top of the page. The top paragraph on page 11 appears to be continued from a different printout than the previous page.

Further, neither CA nor GT repeating nucleotide sequences are the subject of this article.

Accordingly, the Patel reference does not show the requirements of claims 105 and 107

of the present invention. Further, there is no mention of isolated pharmacogenetic markers in the Patel reference required by claims 118-119 of the present invention.

The Nagarkatti article describes the identification of 26 single-nucleotide polymorphisms (SNPs) spanning a total of 147kb in two candidate genes, IL4RA and STAT6, for atopic disorders (Abstract). It also discusses the identification of three novel polymorphic (CA) repeat regions in these genes.

Only by extrapolation it has been mentioned in Nagarkatti that "as the encoded proteins of these genes are a part of single pathway" (Abstract), the functional polymorphisms and their interaction between could lead to susceptibility to atopic disorders. In the present invention, the allelic variants of only the STAT 6 gene have been shown to be associated with high or low risk to atopic asthma. Nagarkatti merely describes the content of STAT 6 and IL4 RA genes. It is therefore clear that association of allelic variants and specific haplotypes of the STAT 6 gene described in the present invention have not been disclosed or suggested by Nagarkatti.

Nagarkatti does not show the association of GT di-nucleotide repeats with atopic asthma as required by claims 105 and 107 in the present invention.

With regard to the rejections of claims 110 and 117, it appears that the haplotypes being claimed are not shown in Nagarkatti. For example, on page 686 of Nagarkatti, there is not any "16 15 [haplotype having] CA repeat 16 on R1 locus and 15 on R3 locus of the STAT6 gene having a p value less than 0.0001" as required by claim 110. Haplotypes 17 14 (p less than 0.0001) and 23 16 (p less than 0.00001) disclosed in claim 117 are also not shown in the Nagarkatti or Patel references.

Furthermore, there is no disclosure or suggestion of isolated pharmacogenetic markers in Nagarkatti as required by claims 118 and 119 of the present invention.

It is respectfully submitted that the products of claims 105, 107, 110 and 117-119 are not anticipated or rendered obvious by the teachings of Patel, Nagarkatti and combinations thereof.

Based on the foregoing, it is respectfully submitted that independent claims 105, 107 and 118-119 are novel and non-obvious. Claims 110 and 117 depend from independent claim 105 and accordingly are allowable for at least this reason, as well as for the separately patentable elements contained in each of the dependent claims.

Accordingly, separate consideration of each of the dependent claims is respectfully requested.


In addition, Applicants deny any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. Any rejections and/or points of argument not addressed would appear to be moot in view of the remarks presented. However, the Applicants reserve the right to submit further arguments in support of the above-stated position, should that become necessary. No arguments are waived and none of the Examiner's assertions are conceded.

Extension of Time

A Petition for a two-month extension of time is also being filed with this Amendment.

The Office is authorized to charge any fees found to be due as a result of this reply or credit any overpayments to this firm's deposit account number 01-0035.

Respectfully submitted,


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